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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2015-0684; FRL-9940-77-ORD]

### Notice of Availability of Draft Guidelines for Human Exposure Assessment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability for public comment.

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**SUMMARY:** The Environmental Protection Agency (EPA) is announcing a 45-day public comment period for the External Review Draft of the “*Guidelines for Human Exposure Assessment*.” EPA is seeking public comment prior to external peer review. The document will undergo review during an expert peer review meeting, which will be convened, organized, and conducted by an independent contractor. The date and location of the peer review meeting will be announced in a subsequent **Federal Register** notice. All comments received in the docket by the closing date **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be shared with the peer review panel for their consideration. Comments received after the close of the comment period may be considered by EPA when it finalizes the document. Members of the public may obtain the draft guidance at <http://www.regulations.gov>; or [www.epa.gov/osa/guidelines-human-exposure-assessment](http://www.epa.gov/osa/guidelines-human-exposure-assessment) or from Dr. Michael Broder via the contact information below.

**DATES:** All comments received in the docket by **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be shared with the external peer review panel for their consideration. Comments received beyond that time may be considered by EPA when it finalizes the document.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2015-0684 by one of the following methods:

- *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *E-mail: ord.docket@epa.gov*.
- *Mail*: ORD Docket, Environmental Protection Agency, *Mailcode*: 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.
- *Hand Delivery*: EPA Docket Center (EPA/DC), Room 3334, EPA West Building, 1301 Constitution Avenue, NW, Washington, D.C. 20460, Attention Docket ID No EPA-HQ-ORD-2015-0684. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-ORD-2015-0684. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected by statute through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in

the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index.

Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

**FOR FUTHER INFORMATION CONTACT:** Dr. Michael Broder, Office of the Science Advisor, Mail Code 8105R, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number (202) 564-3393; fax number (202) 564-2070; or email: [broder.michael@epa.gov](mailto:broder.michael@epa.gov).

**SUPPLEMENTARY INFORMATION:** The current guidance document for human exposure assessment, *Guidelines for Exposure Assessment*, was published in 1992, reflecting the state-of-the-science in the 1970s and 1980s. Since its publication, the field of exposure science has

undergone significant transformation in methods and approaches, which EPA has incorporated into its policies and practices to better align with the current state-of-the-science. The 1992 guidelines are being updated to reflect the updated methods and approaches.

The draft guidelines benefit from over two decades of experience with EPA assessments conducted by Agency programs under their respective authorities and constraints, and from input from external panels, including the National Academy of Sciences and EPA's Science Advisory Board. This draft document builds on topics covered in the 1992 exposure guidelines including planning and scoping for an assessment, data acquisition and use, modeling, and considerations of uncertainty in exposure assessment. It also includes new material on planning and conducting an observational human exposure measurement study and considerations of lifestyles and sensitive populations in exposure assessments. These draft guidelines present the most current science used in EPA exposure assessments and incorporates information about the Agency's current policies.

Dated: December 22, 2015

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EPA Science Advisor

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